

## REMARKS

With this response, claims 86, 90, 93, 94, 97, and 98 are pending. Claim 98 has been amended. Claims 89, 91, 92, and 99-110 were withdrawn by the Examiner as allegedly being directed to a non-elected invention. Claims 87, 88, 95, and 96 were previously canceled without prejudice or disclaimer in Applicants' Response dated September 14, 2007. Applicants reserve the right to prosecute the non-elected subject matter in divisional applications. Support for the foregoing amendments can be found at least, for example, in claim 90 as originally filed.

### **I. Finality of the Last Office Action**

Applicants thank the Examiner for withdrawing the finality of the last Office Action.

### **II. Withdrawn Rejection under 35 U.S.C. § 101**

Applicants thank the Examiner for withdrawing the rejection under 35 U.S.C. § 101 in light of Applicants' arguments filed November 12, 2008.

### **III. Withdrawn Objection to Claim 90**

Applicants thank the Examiner for withdrawing the objection to claim 90 as a product-by-process claim.

### **IV. Rejection under 35 U.S.C. § 102(b) over Fernholz *et al.***

The Examiner has maintained the rejection of claims 86, 90, 93-94 and 97-98 under 35 U.S.C. § 102(b) as allegedly being anticipated by Fernholz and Stavely ("Fernholz"). The Examiner alleges that "[a] structure search of Fernholz *et al.* disclosed the compounds contained in the reference and their chemical structures." See Office Action at page 4. The Examiner further stated that "the compound taught by Fernholz *et al.* contains a double bond on the C-22 carbon. This is proof that during hydrogenation of brassicasterol, the process only reduces the C-5 double bond leaving the C-22 double bond intact. Therefore the brassicastanol compound

anticipates the instant invention.” *Id.* Applicants respectfully disagree with the Examiner’s rejection.

It is well established that, to anticipate a claim, a reference must disclose every element of the claim. *Verdegaal Bros. v. Union Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). “The purpose of the written description requirement is broader than to merely explain how to ‘make and use’; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.” *Vas-Cath Inc. v Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

Fernholz does not disclose brassicastanol. The Fernholz authors did not associate the structure found by the Examiner with the brassicastanol recited in the Fernholz paper. Fernholz does not disclose any structure for brassicastanol, but only states that brassicastanol is “different from ostreastanol.” The Examiner has picked out a molecule from a list of molecules in Table I. See Fernholz at page 142. This is not adequate disclosure of a structure for brassicastanol when, as here, Fernholz merely lists molecules without more. In fact, whatever Fernholz may disclose, it is not brassicastanol as described in the specification, which has 28 carbons. Instead, Fernholz states that “[t]he empirical formula  $C_{29}H_{46}O$  is more probable” for the brassicasterol crystals supposedly isolated. See Fernholz at page 143. As such, Fernholz teaches away from the brassicastanol disclosed in the specification by suggesting that brassicasterol has 29 carbons, instead of 28 carbons. For at least all of these reasons, the brassicastanol structure that the Examiner alleges in her Office action is associated with Fernholz is not what was isolated by Fernholz, nor was it disclosed by Fernholz.

Moreover, Fernholz at best discloses crystals, not an oil containing brassicastanol. Fernholz states that “[t]he ester was recrystallized” and refers to “[t]he crystalline residue left on evaporation of the ethanol.” See Fernholz at page 142 and page 143, respectively. Applicants respectfully submit that Fernholz does not disclose an oil containing brassicastanol. Therefore, Fernholz does not expressly disclose each and every element of the present claims.

Secondly, Fernholz is not enabled. To anticipate, Fernholz must be enabling. “[I]nvalidity based on anticipation requires that the assertedly anticipating disclosure enabled the subject matter of the reference and thus of the patented invention without undue

experimentation.” *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*, 346 F.3d 1051, 68 USPQ2d 1373 (Fed. Cir. 2003). A person skilled in the art at the time of filing of the instant application would recognize that the hydrogenation process disclosed in Fernholz would lead to each double bond in the structure being fully reduced and saturated, resulting in only single bonds. A person of ordinary skill in the art at the time of filing of the instant application would also recognize that there would be no way to control the hydrogenation process disclosed in Fernholz so that the degree of reduction could be chosen or predicted.

This is confirmed by the specification as filed, which teaches that “brassicasterol will be hydrogenated [by a manufacturing process] to 22-dihydro-brassicastanol, in which both the C-5 and C-22 double bonds are reduced.” See specification as filed at page 119, lines 12-16. Therefore, Applicants respectfully submit that Fernholz is not enabled for the claimed subject matter.

As Fernholz neither describes nor enables brassicastanol, Applicants respectfully submit that claims 86, 90, 93-94 and 97-98 are not anticipated by Fernholz and that the rejection of claims 86, 90, 93-94 and 97-98 under 35 U.S.C. § 102(b) is overcome and should be withdrawn.

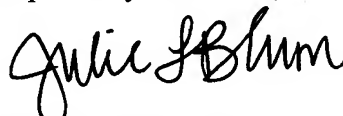
#### **V. Rejection under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph**

Claim 98 stands rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, for allegedly being indefinite “for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” See Office Action at page 7. The Examiner stated that “[c]laim 98 recites the limitation ‘oil is produced in a transgenic seed’ in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. There is no indicating in claim 86 that the oil originates in a transgenic seed.” Applicants respectfully disagree with the Examiner’s rejection. Applicants submit that claim 98 further limits claim 86 and specifies that the oil of claim 86 is produced in a transgenic seed. There is no requirement that this limitation must have an antecedent in claim 86, as the limitation is added in dependent claim 98. Therefore, Applicants respectfully request clarification of the Examiner’s rejection or withdrawal.

## CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-6237 should any additional information be necessary for allowance.

Respectfully submitted,



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Date: August 3, 2009

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